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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,661	09/23/2003	Jean-Claude Yvin	P08424US00/BAS	1057
881 7590 04/30/2009 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 04/30/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/668,661

Applicant(s)

YVIN ET AL.

Examiner

MICHAEL C. HENRY

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/17/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The following office action is a responsive to the amendment filed, 02/17/09.

The amendment filed 02/17/09 affects the application, 10/668,661 as follows:

1. Claim 23 has been amended. Applicant's amendments have overcome the rejection made under 35 U.S.C. 103(a). However, a new ground(s) is set forth herein below.
2. The responsive to applicants' arguments is contained herein below.

Claims 23-34 are pending in the application

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thornton*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23-34 are rejected under the judicially created doctrine of double patenting over claims 1-11 of U. S. Patent No. 6,660,722 B2 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: In claim 1, applicant claims a method to promote the regeneration of the cells in the bone marrow and the peripheral blood of a patient subjected to a chemotherapeutic antineoplastic treatment comprising administration to

said patient of an effective amount of an antineoplastic agent that causes an acute reduction of said cells, said method comprising administration of laminarin to the patient in an amount effective to cause promotion of the regeneration of the cells, the laminarin being administered in conjunction with the administration of the neoplastic agent, wherein said laminarin; has a molecular weight from about 2,500 to about 6,000, and consists essentially of a main linear chain of 15 to 35 glucopyranose units joined by β -(1,3) linkages optionally branched with glucopyranose units linked to the main chain by β -(1,6) linkages, the terminal unit of the main chain being selected from the group consisting of glucose and mannitol. Claims 24-34 are drawn to said method wherein specific antineoplastic agent is use, specific routes and types of administration and the use of soluble laminarin.

Yvin et al., in claim 1, claim a therapeutic method comprising intravenous, intraperitoneal or oral administration of an amount of laminarin, comprised within a composition comprising laminarin and a pharmaceutically acceptable carrier, to a human or to a warm-blooded animal suffering from a tumor, a cancer, a viral disease, a bacterial disease, a fungal disease, a disease of the immune system, an auto-immune disease or a disease related to a deficiency of immunostimulation, in the human or the animal, wherein the amount of laminarin or the concentration of laminarin in the composition is effective to treat the tumor, the cancer or the disease. Claims 2-11 are drawn to the use of specific soluble laminarin, treatment of specific cancers, the use of a chemotherapeutic agent, potentiator and specific dosages of laminarin.

The difference between applicant's claimed method and the method of Yvin et al. is that Yvin et al., does not explicitly claim the promotion of the regeneration of the cells. However, applicant administers the same soluble laminarin and chemotherapeutic agent as Yvin et al. (to

the same patient) and also disclose the laminarin of the same molecular weight and structure as Yvin et al. (see col. 1, lines 40-51) and consequently it is obvious to determine the inherent effects or mechanism(s) (such as the promotion of the regeneration of the cells) by which the laminarin treats or contributes to the treatment of cancer or disease.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to administer laminarin and an antineoplastic agent or chemotherapeutic agent to a patient or human and to determine the inherent effects or mechanism(s) (such as the promotion of the regeneration of the cells) by which the laminarin treats or contributes to the treatment of cancer or disease.

One having ordinary skill in the art would have been motivated, to administer laminarin and an antineoplastic agent or chemotherapeutic agent to a patient or human and to determine the inherent effects or mechanism(s) (such as the promotion of the regeneration of the cells) by which the laminarin treats or contributes to the treatment of cancer or disease in order to improve or optimize the said treatment.

Response to Arguments

Applicant's arguments with respect to claims 23-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be

reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
April 27, 2009.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623